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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	:	Civil Action No. 3:10-CV-01723-JAP-TJB
Plaintiffs and Counterclaim-Defendants,	:	
v.	:	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	:	PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR LEAVE TO AMEND THEIR NON- INFRINGEMENT AND INVALIDITY CONTENTIONS
Defendants and Counterclaim-Plaintiffs.	:	CONFIDENTIAL – TO BE FILED UNDER SEAL

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PRELIMINARY STATEMENT

In flagrant violation of the Local Patent Rules, Defendants Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (together, "Zydus" or "Defendants") attempted to inject previously undisclosed noninfringement and invalidity contentions into this case by way of their expert's report ("Meyer-Stout Report," attached as Ex. 1) in mid-January. Plaintiffs¹ promptly moved to strike the most egregious violation of the Local Patent Rules from the Meyer-Stout Report, based on previously undisclosed prior art (D.I. 132). Now, with its Motion for Leave to Amend its Contentions ("Motion")², Zydus seeks the Court's blessing for all of its previously undisclosed arguments.

In support of its Motion, Zydus provided Plaintiffs with redlined, proposed amendments to its Noninfringement and Invalidity Contentions. Those redlines speak for themselves.

(Ex. 2.) [REDACTED]

Zydus is now seeking to completely overhaul its noninfringement and invalidity case. Zydus' proposed amendments are too much, much too late.

Zydus cannot establish good cause for its proposed amendments. It has not been diligent in arriving at its proposed noninfringement and invalidity positions, and it has unquestionably delayed in seeking leave to amend. Zydus argues that the Court's claim construction decision was a game changer that triggered its [REDACTED]

[REDACTED] But the Court's claim construction was hardly

¹ Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm") (Takeda and Ethypharm together, "Plaintiffs").

² [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

unexpected, since the Court adopted Takeda's proposed claim constructions (as opposed to one that neither side had proposed). [REDACTED]

[REDACTED]

Zydus should not be permitted to sandbag Plaintiffs with brand new noninfringement and invalidity contentions at this late phase of the litigation. With trial mere months away and the [REDACTED] such prejudice simply cannot be cured. The Court should deny Zydus' Motion for Leave to Amend and bar its expert, Dr. Meyer-Stout, from relying on Zydus' belated contentions that were first disclosed in her expert report.

FACTUAL BACKGROUND

This is a patent infringement action under the Hatch-Waxman Act on four patents covering Takeda's Orally Disintegrating Tablet ("ODT") formulation of the blockbuster anti-ulcer drug Prevacid[®].³ [REDACTED]

³ The patents-in-suit include three Takeda patents (U.S. Patent Nos. 6,328,994 (the "'994 patent"), 7,431,942 (the "'942 patent"), 7,875,292 (the "'292 patent")) (collectively, the "Takeda patents") and a patent licensed to Takeda by Ethypharm (U.S. Patent No. 5,464,632 (the "'632 patent")).

Plaintiffs commenced this action on April 5, 2010. (D.I. 1.)

On August 16, 2010, Zydus served its Non-Infringement and Invalidity Contentions. (Ex. 3.) On December 3, 2010, with Plaintiffs' consent and leave of the Court, Zydus served Amended Non-Infringement and Invalidity Contentions. (Ex. 4.) [REDACTED]

The parties exchanged proposed claim constructions on September 21, 2010. *Markman* briefing commenced on December 3, 2010, and concluded on February 8, 2011. A *Markman* hearing was held on May 26, 2011⁴, and on October 5, 2011, the Court issued its claim construction opinion. (D.I. 113.) In relation to "average particle diameter" limitations of the '994 and '942 patents, the Court adopted Takeda's construction that incorporated a $\pm 10\%$ standard of error. On October 19, 2011, Defendants filed their Motion for Reconsideration of Claim Construction based on "average particle diameter". (D.I. 116.) On January 25, 2012, the Court denied Defendants' motion, observing that "Defendants do little more than argue that the Court erred in its claim construction, and they repeat a number of arguments that had earlier been presented to and evaluated by the Court." (D.I. 130 at 2.)

Fact discovery closed in December 2011. Defendants served Paula Meyer-Stout's Expert Report on January 17, 2012. [REDACTED]

⁴ After Zydus amended its paragraph IV certification to include a third Takeda patent, the '292, Takeda served its First Amended Complaint on July 26, 2011, with Zydus' permission and leave of Court. (D.I. 98.) The '292 is a continuation of the '994 and '942 patents-in-suit. The parties stipulated that "the claim disputes for the '292 are identical to those . . . for the '994 and '942" and that "the *Markman* ruling for the '994 and '942 patents . . . will be binding for the claim terms in the '292 patent." (D.I. 96-1.)

[REDACTED]
[REDACTED] Plaintiffs promptly moved to
strike the most egregious violation [REDACTED]

[REDACTED] (D.I. 132.) That motion is pending with the Court.

On February 10, 2012, Zydus filed the instant Motion seeking, yet again, leave to amend its Contentions; its proposed amendments incorporate arguments first raised in the Meyer-Stout Report. Zydus provided Plaintiffs with a redlined version of its proposed Second Amended Contentions (Ex. 2 (redline); Ex. 5 (proposed Second Amended Contentions)). That redline highlights Zydus' many new invalidity and noninfringement arguments directed against the '632 and Takeda patents. Plaintiffs object to a subset of these contentions:

- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The case is moving toward trial this summer. Zydus has not been diligent in arriving at and disclosing its latest noninfringement and invalidity contentions. It is too late now.

ARGUMENT

I. THE LOCAL PATENT RULES REQUIRE PARTIES TO DISCLOSE THEIR CONTENTIONS IN A TIMELY MANNER SO THAT NONINFRINGEMENT AND INVALIDITY ARE NOT MOVING TARGETS

The Local Patent Rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharms., Inc. v. Sandoz Inc.*, Civil Action No. 08-5974 (GEB), 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (internal quotation and citation omitted), *appeal denied, judgment aff'd*, 2010 WL 4789950 (D.N.J. Sept. 8, 2010). "Distinguishable from the liberal standard for amending the pleadings, the philosophy behind amending [invalidity contentions] is decidedly conservative, and designed to prevent the 'shifting sands' approach" to patent litigation. *Id.* (denying leave to amend invalidity contentions).

Under Rule 3.7, amendment to a defendant's invalidity contentions "may be made only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. "[T]he

[REDACTED]

'modest degree of flexibility' that the Rule provides must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early on."

AstraZeneca AB v. Hanmi USA, Inc., Civil Action No. 11-760 (JAP), 2011 WL 5526009, at *4 (D.N.J. 2011) (Bongiovanni, J.) (citation omitted). Rule 3.7 identifies several "examples of

circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause," including "a claim construction by the Court different from that proposed by the party

seeking amendment" and "recent discovery of material prior art despite earlier diligent search."

L. Pat. R. 3.7. "[A] dominant consideration in determining whether good cause exists to permit a requested amendment is the diligence of the moving party." *AstraZeneca AB*, 2011 WL 5526009 at *4.

For the purposes of this Motion, then, Zydus must establish good cause, including its own diligence in seeking amendment, and lack of prejudice to Plaintiffs. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) (placing the burden on the movant); *see also* L. Pat. R. 3.7. Because Zydus can establish none of these, its Motion should be denied.

II. ZYDUS CANNOT ESTABLISH GOOD CAUSE FOR LEAVE TO AMEND ITS NONINFRINGEMENT AND INVALIDITY CONTENTIONS

A. [REDACTED]

[REDACTED]

While it is true that absent undue prejudice, "a claim construction by the Court different from that proposed by the party seeking amendment" *may* support a finding of good cause, that rule "is intended to allow a party to respond to an *unexpected* claim construction by the court." L. Pat. R. 3.7; *Finisar Corp. v. DirecTV Grp., Inc.*, 424 F. Supp. 2d 896, 901 (E.D. Tex. 2006) (emphasis added); *Convolve, Inc. v. Compaq Computer Corp.*, No. 00 Civ. 5141(GBD)(JCF), 2006 WL 2527773, at *3 (S.D.N.Y. Aug. 31, 2006) (same), *reconsideration denied*, 2007 WL 415145 (S.D.N.Y. Feb. 7, 2007). It "does not mean that after every claim construction order, new invalidity contentions may be filed," for that "would destroy the effectiveness of the local rules in balancing the discovery rights and responsibilities of the parties." *Finisar*, 424 F. Supp. 2d at 901; *LML Patent Corp. v. JPMorgan Chase & Co.*, Civil Action No. 2:08-CV-448, 2011

⁶ [REDACTED]

WL 5158285, at *5 (E.D. Tex. Aug. 11, 2011) (same). Simply put, "[a] party cannot," as Zydus does here, "argue that because its precise proposal for a construction of a claim term is not adopted by the court, it is surprised and must prepare new invalidity defenses to meet claims of infringement." *Finisar*, 424 F. Supp. 2d at 901; *Advanced Micro Devices v. Samsung Elecs. Co.*, No. C. 08-00986 SI, 2010 WL 5153136, at *2-3 (N.D. Cal. Dec. 13, 2010) (same). Accordingly, courts have required parties basing proposed amendments on *Markman* rulings to show that the construction at issue "changes the rules of the game." See *ePlus, Inc. v. Lawson Software*, Civil No. 3:09cv620, 2010 WL 3219318, at *2 (E.D. Va. Aug. 13, 2010) (quotation and internal modification omitted).

Zydus cannot credibly argue that the Court's claim construction took it by surprise or changed the rules of the game; the Court adopted Takeda's long-disclosed claim construction (as opposed to adopting one that neither party had proposed).⁷ Zydus has known of Plaintiffs' proposed claim constructions for almost 18 months and the Court's claim construction decision for more than four months. Yet, it delayed disclosing its contentions until a month ago.⁸ Zydus

⁷ See, e.g., *ePlus*, 2010 WL 3219318 at *3 (striking expert report that violated scheduling order and holding that defendant "failed to carry its burden to show that the Court's construction . . . changed the rules of the game" where the construction at issue "was the very same agreed to by [the plaintiff] at the Markman hearing"); *MASS Engineered Design, Inc. v. Ergotron, Inc.*, 250 F.R.D. 284, 286 (E.D. Tex. 2008) ("[T]he Court adopted all of DMLP's proposed constructions, without major modification. Thus, MASS was on notice of the possibility of the Court's constructions."); *Nike, Inc. v. Adidas Am. Inc.*, 479 F. Supp. 2d 664, 669 (E.D. Tex. 2007) ("Nike does not explain why the court's construction was so different that amended infringement contentions were necessary. . . . While the court did not specifically adopt either of the parties' proposals . . . [its] definition was not so different from the parties' proposal[s] as to warrant amended infringement contentions based on the claim construction."); *Finisar*, 424 F. Supp. 2d at 901 ("DirecTV did not adequately explain how the court's definition of any of the terms in dispute was so surprising, or differed so greatly from the proposals made by the parties, that it justifies admission of new prior art references two weeks before Finsar's [sic] deadline to submit rebuttal expert reports.").

⁸ Faced with similar delays, courts routinely deny leave to amend. See, e.g., *Oracle Am., Inc. v. Google Inc.*, No. C 10-03561 WHA, 2011 WL 3443835, at *3 (N.D. Cal. Aug. 8, 2011) (holding

has not been diligent in arriving at its proposed contentions or seeking leave to amend. There is no good cause to inject them into the case now.

B. [REDACTED]

This attempt by Zydus to repackage claim construction arguments as invalidity arguments should be rejected.

that "Google failed to exercise diligence in seeking to supplement its invalidity contentions" because it waited "until a month after" the claim construction ruling to seek leave to amend and filed its motion one month after that); *see also O2 Micro*, 467 F.3d at 1367-68 (affirming district court's ruling that three-month delay showed lack of diligence).

C. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] It is too late for Defendants to inject this latest permutation into this case.

[REDACTED]

[REDACTED] Zydus was aware of the issue long before the Court's Claim Construction Decision because the Court resolved claim construction of the relevant limitation as Zydus proposed (by concluding there was no need for construction). (D.I. 113, at 17.) [REDACTED]

[REDACTED] The Court should reject Zydus' attempt to inject this new contention into the case.

D. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs moved to strike that argument, and that motion is currently pending before the Court. (D.I. 132.) Plaintiffs hereby incorporate the arguments set forth in that submission by reference.¹⁰

¹⁰ Zydus cannot save this theory by including it in its Motion for Leave to Amend. For the same reasons that courts strike expert reports violating the Local Patent Rules, they also deny concurrent motions to amend. *Fleming v. Escort, Inc.*, No. CV 09-105-S-BLW, 2011 WL 1542126, at *6 (D. Idaho Apr. 21, 2011) (denying defendant's request for leave "to amend its invalidity contentions to add any of Dr. Grindon's opinions that are deemed new" in response to Plaintiff's motion to strike because defendant "failed to carry its burden under Local Patent Rule 3.7 to show good cause"), *amended on reconsideration on other grounds*, 2011 WL 2173796 (D. Idaho June 2, 2011); *Anascape, Ltd. v. Microsoft Corp.*, Civil Action No. 9:06-CV-158, 2008 WL 7180756, at *1 (E.D. Tex. May 1, 2008) (striking previously undisclosed invalidity contentions from an expert report and denying leave to amend).

¹¹ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Again, leave to amend should be denied.

E.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

There is no good cause for Zydus' amendment. [REDACTED]

[REDACTED]

[REDACTED] But Defendants cannot contend that the Court's decision was somehow unexpected. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹² See Notice Letter (Feb. 15, 2010) at 62, attached as Ex. 7; Defendants' Non-infringement and Invalidity Contentions (Aug. 16, 2010) (Ex. 3); Defendants' Amended Non-infringement and Invalidity Contentions (Dec. 3, 2010) (Ex. 4).

¹³ [REDACTED]

[REDACTED]

[REDACTED] Takeda recently filed its Motion for Spoliation Sanctions in the Form of Exclusion of Zydus' Evidence of Particle Size Testing on Pre-Tableted Granules, dated February 21, 2012. (D.I. 145.) That Motion is currently pending.

[REDACTED]

[REDACTED]

F. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*See, e.g.*, Ex. 2 (Zydus' redlined proposed amendments), [REDACTED])

[REDACTED]

[REDACTED]

[REDACTED]

As before, Zydus has shown no good cause for amendment. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

14 [REDACTED]

[REDACTED]

Zydus' proposed amendment lacks any merit whatsoever and should be rejected.

III. IF THE COURT GRANTS ZYDUS LEAVE TO AMEND, PLAINTIFFS WILL BE SUBSTANTIALLY PREJUDICED BY ZYDUS' BRAND NEW THEORIES ON THE EVE OF TRIAL

"Only if the moving party is able to show diligence may the court consider the prejudice to the non-moving party." *Genentech, Inc. v. Trustees of Univ. of Penn.*, No. 10-CV-02037-LHK, 2011 WL 4965638, at *1 (N.D. Cal. Sept. 16, 2011); *see also O2 Micro*, 467 F.3d 1355 at 1368 ("Having concluded that the district court could properly conclude that O2 Micro did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to MPS."). As discussed above, Zydus cannot prove diligence in moving to amend its noninfringement and invalidity contentions, and its Motion should be denied on this basis alone. Accordingly, the Court need not consider the substantial prejudice Plaintiffs will suffer if Zydus' last-minute amendments are allowed into this case.

Nonetheless, taking Plaintiffs' prejudice into account compels denial of Defendants' motion.¹⁵ This case is in its final phase. [REDACTED] and the Court has suggested that a trial in late spring/early summer would be in order. Plaintiffs have based their litigation strategy on Defendants' timely and disclosed contentions. *King Pharmaceuticals*, 2010 WL 2015258 at *5 (observing that amendments late in the case would "ultimately prejudice Plaintiffs" where their "litigation strategy is based upon Sandoz's originally served Invalidity Contentions"). By not moving to amend earlier, Zydus "telegraphed" an intention to stand on its contentions. *See Oracle*, 2011 WL 3443835 at *4. Now, with this Motion, Zydus seeks to reconfigure its noninfringement and invalidity case with a host of new

¹⁵ Of course, Defendants bear the burden of proving lack of prejudice to Plaintiffs. *See* L. Pat. R. 3.7; *Fleming*, 2011 WL 1542126 at *4. Despite that burden, Zydus focuses on the prejudice it will purportedly suffer if its Motion is denied. Not only is such prejudice of questionable relevance, it is entirely of Defendants' own making, and should thus be disregarded.

theories. But Plaintiffs should not have to scramble to counter Zydus' brand new theories on the eve of trial. *See Tyco Healthcare Grp. LP v. Applied Med. Res. Corp.*, Civil Action No. 9:06-CV-151, 2009 WL 5842062, at *3 (E.D. Tex. Mar. 30, 2009) (finding prejudice and observing that "[w]hether or not Tyco would have to perform in-depth analysis or undertake a great deal of discovery to rebut Applied's assertions is irrelevant; the point is that Applied should have, and did not, disclose the combination in a timely manner"). Significantly, any attempt to cure the prejudice to Plaintiffs by further delaying the proceedings will push back trial, endanger the 30-month stay and/or trigger the "fire drill" of a preliminary injunction motion. In any event, forcing Plaintiffs to incur the costs and suffer the delays necessary to respond to Zydus' last minute arguments constitutes prejudice. *King Pharmaceuticals*, 2010 WL 2015258 at 5; *Finisar Corp.*, 424 F. Supp. 2d at 902; *Nike*, 479 F. Supp. 2d at 669-70.

Because of substantial prejudice to Plaintiffs, Zydus' Motion should be denied.

CONCLUSION

For the reasons set for above, Plaintiffs respectfully request that the Court deny Zydus' Motion for Leave to Amend and bar its expert, Dr. Meyer-Stout, from relying on Zydus' belated contentions that were first disclosed in her expert report.

Respectfully submitted,

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